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BEFORE THE UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

ENVIRONMENTAL TOBACCO SMOKE:
A GUIDE TO WORKPLACE SMOKING POLICIES

EPA/400/6-90/004

RESPONSE OF R. J. REYNOLDS TOBACCO COMPANY

OCTOBER 1, 1990

VOLUME II-B

COMMENTS OF RJRT SCIENTISTS

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Comments on:

ENVIRONMENTAL TOBACCO SMOKE:

A GUIDE TO WORKPLACE SMOKING POLICIES

[Draft] EPA 400/6-90/004

Response Addressing:

Chapter 1: What Is ETS?

Section: Toxins and Irritants

Topic: Carbon Monoxide (CO)

Chapter 3: Health Effects of ETS

Section: People With Heart Disease

Section: Heart Disease

Section: Respiratory Disease

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October 1990

SUMMARY: The statements in the EPA public review Draft document, "Environmental Tobacco Smoke: A Guide to Workplace Smoking Policies,"concerning alleged toxicity and irritancy of CO and alleged health effects of ETS are irrelevant and alarmist. The minute concentrations of CO measured in ETS fall below all regulatory standards and produce no significant effect on aerobic capacity or cardiovascular function. The unsubstantiated insinuation that ETS is somehow associated with "heart disease," or exacerbates its effects, is at best hypothetical. Studies presented as evidence for positive correlation between ETS and respiratory disease in adults and children are inconsistent and structurally weak. Data concerning children are totally irrelevant for workplace environments.

COMMENTARY: Commentary is presented in four parts: (1) Toxins and Irritants -- Carbon Monoxide; (2) Health Effects of ETS; (3) Respiratory Disease in Adults; and (4) Respiratory Disease in Children.

1. Toxins and Irritants -- Carbon Monoxide

Summary: In contrast to the statements in the EPA document "Environmental Tobacco Smoke: A Guide to Workplace Smoking Policies," the combined evidence that CO concentrations in office buildings do not exceed 9 ppm and that COHb concentrations associated with exposure to as much as 9 ppm CO do not induce any alterations in cardiovascular function, even in cardiovascularly compromised segments of the population, suggests that inclusion of ETS CO as a meaningful toxicant or irritant in the EPA document

is misleading in the context of the EPA discussion.

Commentary: The Guide notes "carbon monoxide is a gas that interferes with the ability of the blood to carry oxygen" [The Guide, p. 9] and that ETS adds "to the body burden of carbon monoxide from other environmental sources" [The Guide, p. 9]. The EPA implies that ETS significantly contributes to indoor air carbon monoxide ("CO"), concentrations and results in nonsmokers being deprived of normally available oxygen. This is not an accurate representation of the quantitative impact of ETS CO concentrations on the environment nor is it correct to assume that biological effects associated with exposure to high concentrations of CO are likely to occur at concentrations found in ETS.

The highest CO concentration in office buildings reported by Carson and Erickson, 1988, was 8.7 ppm without correction for ambient CO concentrations from outside sources. Even so, all concentrations measured were below EPA's own established standard of 9 ppm [EPA-Air Quality Criterion for CO] and well below the OSHA TLV of 35 ppm for an 8-hour work period [Fed. Reg., January 19, 1989]. In addition, 13 of 23 offices evaluated by Carson and Erikson, 1988, in which smoking took place were below the outdoor concentrations of CO. These data show that CO concentrations in office buildings do not increase significantly as a result of ETS. Thus, the contribution of ETS to ambient CO concentrations in the workplace must be considered insignificant.

Horvath and Bedi, 1988, exposed nonsmoking men to 0 or 9 ppm CO for 8 hours at both sea level and at a simulated 2134 meters. They measured each individual's ability to perform a maximal aerobic capacity test. Results indicated that COHb

concentrations associated with exposure to as much as 9 ppm CO do not induce alterations in cardiovascular functions.

Sheps et al., 1987, examined 30 patients with ischemic heart disease and found no significant effects of COHb levels of 3.8% on either resting or exercise hemodynamics. The time to onset of angina, the duration of angina, and electrocardiophysiologic parameters were not altered by this concentration of COHb. This COHb concentration is five times those measured in the Horvath study in which individuals were exposed continuously for 8 hours to CO concentrations greater than those measured by Carson and Erikson, 1988, for office buildings.

In their review of CO and the production or aggravation of cardiovascular disease processes, Weir and Fabiano, 1982, indicated that the available studies suggest that concern is largely unwarranted. They found no convincing evidence that chronic CO exposure increases the risk of clinically significant atherosclerotic disease. They also concluded that low to moderate CO exposure does not adversely affect cardiac rhythm in man.

In addition, cardiovascular studies that support the national ambient air-quality standards for CO have been investigated by a committee formed by the EPA which concluded that the Agency should not rely on the results.

The combined evidence that CO concentrations in office buildings do not exceed 9 ppm, and that COHb concentrations associated with exposure to 9 ppm or more do not induce any alterations in cardiovascular function, even in compromised segments of the population, suggests that the inclusion of ETS CO as a toxicant or irritant in the EPA

document is misleading in the context of an ETS discussion.

2. Health Effects of ETS -- Heart Disease

Summary: The paucity of meaningful data on the alleged relationship between ETS exposure and heart disease and the failure of EPA, by its own admission, to conduct a complete analysis of the few available data on this relationship necessitate deletion of this section from the EPA document "Environmental Tobacco Smoke: A Guide to the Workplace Smoking Policies."

Commentary: The EPA document includes two references to heart disease in Chapter 3; these are heart disease and people with heart disease.

In the heading associated with "people with heart disease," [The Guide, p. 17] the EPA suggests that exposure to CO from ETS results in alterations of cardiovascular dynamics in individuals already compromised with coronary vascular disease. The discussion above describes both the extremely minimal exposure to CO that individuals are likely to encounter from ETS and the lack of the effects on both compromised and healthy individuals of concentrations in excess of those found in ETS. Again, the EPA uses the excuse that it has not conducted a complete analysis of the information.

In the case of heart disease [The Guide, p. 18], the EPA refers to epidemiologic studies in which the relationship between heart disease and ETS exposure was examined. The EPA itself concludes that these data are insufficient to conclude that ETS

causes heart disease. The EPA indicates that it has not conducted a full review of the literature, yet it suggests that an association may exist. This is simply an inadequate reason for the EPA to include the topic of heart disease in the chapter of health effects of ETS.

The National Research Council (NRC, 1986) reviewed the studies of Garland, Gillis, Hirayama and Svendsen which are referenced by the EPA. At that time, the NRC concluded that, overall, these studies showed (a) no statistically significant effects of ETS exposure on the heart rate or blood pressure of resting healthy men, women, and school age children, (b) no difference in the cardiovascular changes observed in exercising men and women exposed to ETS and to non-ETS conditions, and (c) despite the plausibility of cardiovascular morbidity and mortality, no statistically significant effects of ETS except for those reported in the Hirayama study of a Japanese population.

The Hirayama study has been criticized by many reviewers because of many methodological problems, including the misclassification of smokers and nonsmokers, misclassification of dose response, ignoring workplace exposure, omission of control for indoor air pollution such as cooking with kerosene stoves, and utilization of a non-representative sample of the Japanese population. The inclusion of the heading "heart disease" in a document which, at first review, masquerades as a scientific compilation of accepted fact is misleading and puts undue and unfair emphasis on the completely unproven hypothesis that ETS exposure and the development of heart disease are related. The uncertainty of the current knowledge of the relationship between ETS and the development of heart disease should be presented in the EPA's Policy Guide.

3. Respiratory Disease in Adults

Summary: Because the eleven studies in which the relationship between ETS and pulmonary function in adults was examined employed questionable data collection techniques and gave discordant results, it is not possible for the EPA to conclude that any significant relation exists in adults between ETS and pulmonary function. This section in the EPA document "Environmental Tobacco Smoking: A Guide to Workplace Smoking Policies" requires drastic revision. Since the relationship between exposure to ETS and respiratory diseases/symptoms in children is not pertinent to a discussion of workplace concentrations and exposure to ETS, this section should be deleted from the EPA document "Environmental Tobacco Smoke: A Guide to Workplace Smoking Policies."

Commentary: Eleven studies reviewed the relationship between ETS exposure and pulmonary function in adults (Schilling et al., 1977; White and Froeb, 1980; Comstock et al. 1981; Kauffmann et al. 1983; Salem et al., 1984; Lebowitz, 1984; Brunekreef et al., 1985; Hosein and Corey, 1986; Svendsen et al.,1987; Kauffmann et al., 1989; Hole et al., 1989). Of these numbers, four found differences in one or more parameters of respiratory function associated with ETS exposure, seven did not. In those in which a reduction in one parameter of pulmonary function was reported, the degree of reduction was small (3-15%) and must be considered to be of questionable clinical significance (Bates, 1989; Miller, 1986). In addition, the majority of these studies employed questionnaires and household or spousal smoking as an index of ETS exposure, both of which predispose to the misclassification of

smoking status and exposure estimate.

Eight studies evaluated the relationship of ETS exposure and respiratory symptoms and/or disease as endpoints (Schilling et al., 1977; Simecek, 1980; Comstock et al., 1981; Lebowitz, 1984; Gillis et al., 1984; Kalandidi et al., 1987; Kauffmann et al., 1989; Hole et al., 1989). The findings were equally divided, with four studies reporting positive relationships and four without such relationships. These studies were too variable in their findings to support a unified interpretation regarding ETS and respiratory disease in adults.

Acute exposure in normal individuals generally fails to demonstrate adverse effects of short term ETS exposure on pulmonary function (Pimm et al., 1978; Shephard et al., 1979a). Similar studies in asthmatics have yielded inconsistent results (Shephard, 1977; Dahms et al., 1981; Knight and Breslin, 1985; Wiedemann et al., 1986; Stankus et al., 1988).

Based upon available literature on the subject of respiratory disease and ETS exposure, conclusions regarding potential relationships between ETS exposure and respiratory disease are not possible. In addition, the minimal magnitude of the measurable responses found to be statistically significant suggests that the results are of no clinical significance.

4. Respiratory Disease in Children

Summary: Studies presented as evidence for positive correlation between ETS and respiratory disease in children are inaccurate and totally irrelevant.

Commentary: Several points must be considered in interpreting the findings regarding the association between parental smoking and increased incidence of respiratory symptoms and diseases in children. Witorsch, 1989, reviews the studies and makes several important observations. He identifies a number of factors that could account for the findings in this area, including socioeconomic status of the participants. Further, the studies relied upon questionnaires which are considered inaccurate. The mechanisms of action for the observed changes are unexplained and the variability of the observations increases with increasing age of the children studied. Finally, data regarding children are not significant to a discussion of workplace concentrations of ETS.

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EDUCATION

B.S. (Aeronautical and Astronautical Engineering)
1969 - The Ohio State University

M.S. (Biomedical Engineering and Physiology)
1973 - The Ohio State University

Ph.D. (Biomedical Engineering and Physiology)
1978 - The Ohio State University

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EMPLOYMENT HISTORY

R. J. Reynolds Tobacco Co., Winston-Salem, North Carolina.

Master R&D Toxicologist, Applied Toxicology Group, December 1988 to the present

Senior Staff R&D Toxicologist, Applied Toxicology Group, December 1985 to December 1988

Battelle's Columbus Division, Columbus, Ohio.

Associate Section Manager, Toxicology and Health Sciences, October 1985 to December 1985.

Senior Research Scientist, Toxicology and Health Sciences Section, October 1984 to October 1985; Principal Research Scientist, Health and Environmental Sciences Section, May 1980 to October 1984; Research Scientist, Bioengineering/Health Sciences Section, 1977 to May 1980.

The Ohio State University, Columbus, Ohio.

Adjunct Assistant Professor, Department of Medical Pharmacology, August 1980 to June 1985; Research Associate, Departments of Medicine and Aeronautical and Astronautical Engineering, 1973 to 1977.

General Electric Company, Evandale, Ohio.

Aeronautical and Astronautical Engineering, Aircraft Engine Group, 1969 to 1971.

RELEVANT EXPERIENCE IN TOXICOLOGY

R.J. Reynolds Tobacco Company

Group leader for physiology on more than seven nose-only inhalation toxicology studies designed to evaluate company products.

Study monitor on 17 different extramural toxicology or toxicology-related studies. Major contributions include study design, inhalation system evaluation, study-monitoring and report preparation.

Battelle Columbus Laboratories

Manager of Battelle Columbus Laboratories' Inhalation Toxicology Facility and senior scientific advisor for inhalation studies for the period from 1983 to December 1985.

National Toxicology Program approved study director for inhalation toxicology projects.

Principal investigator and proposal author of a 36-month, Government-funded study to quantify the sequelae of pathophysiology results from acute organophosphate exposure. Pulmonary, cardiovascular, and neuromuscular physiology evaluations as well as routine toxicology endpoints were evaluated in three species exposed by inhalation, intravenous and subcutaneous infusion.

Principal investigator and aerosol physicist for numerous industrially-sponsored inhalation toxicology programs.

Pulmonary physiologist for an 18-month Government-funded program to establish exposure standards for airborne fibrous glass.

Pulmonary physiologist for a large industrial program designed to evaluate the potential toxicity of flyash in normal and compromised populations.

PROFESSIONAL MEMBERSHIPS

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RESEARCH INTERESTS

Toxicology, Inhalation Toxicology
Cardiovascular Physiology
Respiratory Physiology
Fluid Dynamics
Aerosol Physics
Biomedical device Design

PUBLICATIONS AND PRESENTATIONS

Mosberg, A.T., "An in vitro study of transendothelial albumin transport in the presence of a sinusoidally oscillatory flow", Masters Thesis, Ohio State University (1973).

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Nelson

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Comments on:

ENVIRONMENTAL TOBACCO SMOKE:

A GUIDE TO WORKPLACE SMOKING POLICIES

[Draft] EPA 400/6-90/004

Response Addressing:

Chapter 1: What Is ETS?

Section: Measuring ETS in the Air and Body

Topic: Diffusion

Prepared by:

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R.J. Reynolds Tobacco Company

October 1990

SUMMARY: The statement "Researchers have found that ETS diffuses rapidly through buildings, persists for long periods after smoking ends, and represents one of the largest sources of indoor particle pollution" found in the key points section (Chapter 1, page 3) of the EPA draft document "Environmental Tobacco Smoke: Guide to Workplace Smoking Policies" is misleading and incorrect. Problems with the statement are described.

COMMENTS: The Key Points Section [The Guide, pp. 3, 4] of the EPA draft document "Environmental Tobacco Smoke: Guide to Workplace Smoking Policies" [referred to as the "Guide" hereafter], contains an unsubstantiated, misleading argument which is central to the justification of the authors' conclusion. This comment was written to address the statement "Researchers have found that ETS diffuses rapidly through buildings, persists for long periods after smoking ends, and represents one of the largest sources of indoor particle pollution." This statement is inaccurate and misleading. A more appropriate statement is "Measurements have shown that ETS is diluted rapidly in buildings, and it is frequently difficult to determine whether or where smoking has occurred. Most ETS constituents are removed rapidly from building interiors by dilution with fresh air infiltrating the building or introduced into the air handling system. A few ETS components such as nicotine have been shown to readily adsorb onto and desorb from interior surfaces. Because of this behavior, these components are unreliable indicators of exposure to ETS. ETS can be a major source of particles in smoking areas, but may be only a minor source of particulate pollution in non-smoking areas within the same building." The flaw in the Guide's statement is explained below.

The term "diffuses" implies that ETS is found at similar concentration throughout a building, even when the source is well removed from the measurement site. ETS can be distributed in buildings with recirculated air. But, in the process, ETS constituents are rapidly diluted to insignificant concentrations. Problems with mathematical models of others which assume rapid diffusion and good mixing in indoor air spaces are outlined by Kim *et al.*[1]. In addition, Kim has showed through modeling that ETS is rapidly removed from an office space once smoking has stopped [1].

A number of studies have been performed in office buildings which not only have segregated smoking areas, but also rely on some recirculated air for ventilation (a typical situation). Sterling examined the influence of ventilation and smoking-rate parameters on ETS concentrations in indoor environments [2]. His data indicated minimal recirculation of ETS between smoking and nonsmoking areas -- areas on different floors or within different sections of a single large room. In his study, smoking and nonsmoking areas of a cafeteria (which were neither separately ventilated nor physically separated (could be distinguished by nicotine or RSP measurements. In this case, different concentrations of ETS components were measured within the same room. Concentrations were lower in areas further from the cafeteria, even though served by the same ventilation system [2]. Sterling's work supports Kim's conclusions regarding the existence of concentration gradients within the same room [1]. Sterling also found that nicotine concentrations were below the detection limit in nonsmoking offices [2] -- offices that shared recirculated air from the cafeteria. RSP concentrations were also low and apparently unaffected by ETS [2].

In a large volume university amphitheater where a few students smoked between classes, Arfi [3] measured either no or low nicotine concentrations. The reason given for the lack of nicotine was "dilution into the large air volume and good ventilation of the amphitheater."

One of the most detailed studies reported was performed in an "energy efficient" office building. The heating, ventilating and air conditioning (HVAC) system provided air to the offices at three air changes per hour, and had a maximum recirculation rate of 84%. Although the maximum recirculation rate is rarely used; the actual recirculation rate varied throughout the day. Chromatographic profiles of the atmospheres in multiple-occupant offices with one or zero smokers were similar[4]. Lack of difference between chromatographic profiles of air from smoker's and non-smoker's offices has also been reported by others [5]. Nicotine concentrations were considerably lower in offices in which no smoking occurred, than those in offices on the same or different floors in which smoking occurred. When total RSP was examined, there was little difference among the offices [4]. However, a method to estimate the contribution of ETS to total RSP has been developed [6] and was applied in the study[4]. The apportionment technique showed that ETS contributed only <6% to 40% toward the total RSP in the building. In one non-smoker's office, a mean RSP concentration of 52 $\mu g/m^3$ was measured, to which ETS contributed a maximum of 3 $\mu g/m^3$. The highest RSP concentration, 148 $\mu g/m^3$, was measured in the office of a smoker. However, of this total, only 61 $\mu g/m^3$ were attributable to ETS. The

majority of the particulate matter in each of these offices arose from sources other than ETS [4].

Nicotine has been demonstrated to be an inadequate marker for ETS exposure because its ratio to other ETS constituents is highly variable [7-12]. The origin of the variation is probably due to non-first order decay kinetics and its ability to reversibly adsorb on surfaces [7,8]. Most other ETS constituents studied to date appear to follow first order decay kinetics with a decay rate constant nearly equal to the air exchange rate [7,8]. The office study found that, in general, total and specific volatile organic compounds showed no relationship to smoker density or number of smokers in an office [4].

Removal of ETS from an interior environment is proportional to air exchange rate. If a building is properly ventilated, the process should be both rapid and efficient. It has been clearly demonstrated [7,8,13] that most ETS constituents (for which measurements have been made) are removed from a room at a rate proportional to the air exchange rate. Nicotine is an exception to this rule. Nicotine has a demonstrated ability to reversibly adsorb onto interior surfaces and smoker's clothing and self [7,8]. For example, nicotine has been detected in aircraft and buildings long after smoking occurred and other ETS constituents were removed by air exchange. Also, significant desorption of nicotine from a smoker was demonstrated in a controlled environment test chamber in the absence of ETS production [7].

The contribution of ETS to indoor air particulate matter has been addressed several times in the literature. Making the assumption that all indoor air RSP is attributable to ETS is not valid. Likewise, one cannot assume that indoor air background RSP values are equal to outdoor values (although they sometimes are). The office study of Baker [5] clearly illustrates this point, as do the studies of Oldaker *et al.* [6,14].

Although ETS may affect indoor air quality, it is neither the only nor the most serious problem with indoor air quality. This is shown by two studies of sick building syndrome. One company studied indoor air quality in over 39 million square feet of property between 1981-1987 (223 buildings), ETS was found to be the most significant pollutant in only 4% of the buildings [15]. In another sick building database, smoking was implicated as the problem in only 12 of 408 (<3%) of the buildings surveyed [16]. Despite this compelling body of work, the EPA document recommends major efforts to control a relatively minor (albeit visible) factor in indoor air quality. Furthermore, the smoking bans suggested in the report will do nothing to correct unseen or unnoticed problems with indoor air quality which may have more serious health consequences than ETS. That banning smoking will make indoor air "safe", as is deceptively implied in the document, is not justified on the basis of indoor air quality research.

RECOMMENDATIONS: The statement, "Researchers have found that ETS diffuses rapidly through buildings, persists for long periods after smoking ends, and represents one of the largest sources of indoor air particle pollution," found in chapter one, page 3 should

be eliminated or rephrased to read "Measurements have shown that ETS is diluted rapidly in buildings, and it is frequently difficult to determine whether or where smoking has occurred. Most ETS constituents are removed rapidly from building interiors by dilution with fresh air infiltrating the building or introduced into the air handling system. A few ETS components such as nicotine have been shown to readily adsorb onto and desorb from interior surfaces. Because of this behavior these components are unreliably indicators of exposure to ETS. ETS can be a major source of particles in smoking areas, but may be only a minor source of particulate pollution in non-smoking areas within the same building."

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Curriculum Vitae

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Education

Georgia Institute of Technology, Ph.D., 1987, Analytical Chemistry, Thesis title: "Applications of Analytical Collisional Mass Spectrometry"

Hampden-Sydney College, B.S., 1983, Chemistry (ACS Certified)

Employment

Dec. 1987 - Present: R.J. Reynolds Tobacco Company, R&D Chemist

Responsible for conceiving, planning, executing and interpreting research on the chemical composition of tobacco and tobacco smoke and the chemistry of environmental tobacco smoke (ETS). Major areas of research have included the decay and fate of ETS constituents, factors which influence non-smokers perceptions of environmental tobacco smoke, and development of methods for studying the cytotoxicity and genotoxicity of ETS.

Summers 1979-1983: Chomerics Inc., Associate Scientist, Laboratory Technician

Responsible for the development of processes for the production of electrically conductive metallic and non-metallic powders, analysis of plated powders using a scanning electron microscope equipped with an energy dispersive X-ray analysis probe, and the compounding and testing of materials with unique electrical and thermal properties.

Publications

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Comments on

ENVIRONMENTAL TOBACCO SMOKE: A GUIDE TO WORKPLACE SMOKING POLICIES

[Draft] EPA 450/6-90/004

Chapter 1: What Is ETS?

Toxins and Irritants

Carbon Monoxide (CO)

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SUMMARY

The statements made about carbon monoxide (CO) from ETS are imprecise and inordinately brief and therefore are misleading. These statements will provide decision-makers with a false understanding of the effects of CO exposure from ETS. Major problems with the Guides discussion of CO from ETS include: (a) neglect of toxicological principles and (b) failure to recognize that exposures are neither analytically nor biologically significant.

Specific comments are provided below.

ITEM 1. The Guide states on p.9 under **Toxins and Irritants:**

> In addition to its carcinogenic constituents, ETS contains a variety of other chemicals that are harmful to humans. Examples include:
>
> **Carbon monoxide** is a gas that interferes with the ability of the blood to carry oxygen. Carbon monoxide levels increase when smokers are present, adding to the body burden of carbon monoxide from other environmental sources.

COMMENTS

1. **Neglect of toxicological principles** The introductory paragraph implies that because CO, hydrogen cyanide, ammonia, and nicotine are present in ETS and because these substances above certain exposure levels *can* be harmful to humans, humans are therefore harmed by exposure to these substances when found at extremely low levels in ETS. This logic is flawed because of the authors' failure to recognize fundamental toxicological principles. Put

simply, there is no evidence that CO from ETS either has harmed or could possibly harm humans at *realistic* ETS concentrations. Realistic ETS concentrations are emphasized here, to distinguish data that can be applied to the workplace from data reported in studies where concentrations of ETS were unrealistically high.

2. **Relative insignificance of exposure** In almost all settings where exposure of the public to ETS can occur, exposure to CO from ETS is insignificant relative to CO exposures originating from other sources. In general, automobiles are *the* major source of CO measured both indoors and outdoors, a fact which is reflected by the need to measure CO both indoors and outdoors to characterize its effect on indoor air quality accurately. Other sources, far more important than ETS, include gas-fired appliances and space heaters.

3. **Significance of increase in CO levels with smokers** The statement "Carbon monoxide levels increase when smokers are present" is misleading and to some extent inaccurate. It implies that whenever smokers are present, a measurable, and therefore analytically significant, increase in the CO level occurs. The scientific literature supports neither the statement nor its implication.

Field surveys to assess ETS exposure show that CO concentrations do not correlate significantly with smoking activity. (See, for example, Carson and Erikson [1].) Most scientists engaged in exposure assessment recognize that the utility of CO as an indicator of ETS exposure is limited essentially to laboratory settings because of the general inaccessibility in field settings of representative locations for collecting outdoor samples. (Aircraft cabins are an exception because outdoor CO does not contribute significantly to indoor CO concentrations.) As noted above, the literature shows that most, if not all,

of these experiments in laboratory settings involved unrealistically high levels of smoke – concentrations much higher than would be associated with ETS.

4. **Meager data base on exposure to CO from ETS** The literature contains very few studies which attempt to quantify exposure to CO from ETS. To quantify such exposure accurately requires measurements both inside and outside of the environments studied – an apportionment procedure which allows estimation of the contribution of outdoor sources of CO to levels of CO observed indoors. Because ETS is a minor source of CO and because CO is not specific for ETS, estimates of exposure to CO from ETS in field settings are imprecise. For this reason, most scientists engaged in exposure assessment do not view CO as a reliable (or even a useful) indicator of exposure to ETS.

5. **Biological significance of exposure** The passage also implies that both exposure to CO from ETS and the consequent body burden of CO from ETS are biologically significant: no evidence exists to support either of these implications. Indeed, the literature is replete with conclusions that carboxyhemoglobin is not an adequate indicator of exposure to ETS.

The National Research Council [2] addressed this issue:

> "In sum, however, measurements of exhaled CO and of [carboxyhemoglobin] are not useful indicators of exposure to ambient ETS except in acute exposure studies in the laboratory."

6. **Exposure in Relation to Standards** The CO levels found in most environmental settings are substantially lower than the EPA National Ambient Air Quality Standard (NAAQS) and the National Institute of Occupational

Safety and Health (NIOSH) standard. If, for sake of argument, one accepts the EPA's stated and implied positions, namely, that CO from ETS is:

(a) harmful to humans;
(b) interferes with the ability of the blood to carry oxygen;
(c) adds to the body burden of carboxyhemoglobin; and, therefore,
(d) is biologically significant under realistic conditions of exposure,

then the level of the primary NAAQS for CO must be inadequate; consequently, the standard should be revised. This author is unaware of any science suggesting the inadequacy of the current NAAQS.

The Guide is inconsistent on the matter of citing standards; e.g., on p. 12, standards are invoked to address results from determinations of ETS RSP in homes. Why is it that the Guide does not use standards in connection with the brief discussion of CO from ETS?

7. **Absence of literature citations** Literature citations to support the statements in this paragraph would be helpful and would enhance technical quality by ensuring completeness.

RECOMMENDATION

The EPA must either strike the paragraph on CO or include all of the following: (a) provide an average CO exposure for environmental categories of interest to the intended users; (b) put exposure to CO from ETS in perspective by giving average ambient levels associated with either urban settings or EPA or NIOSH standards; and (c) note that neither CO nor carboxyhemoglobin is a reliable indicator of ETS exposure.

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CURRICULUM VITA

Dr. Guy B. Oldaker III

PERSONAL INFORMATION

Address:

REDACTED

EDUCATION

1972, B.A., Chemistry, University of Virginia
1979, Ph.D., Chemistry, Virginia Polytechnic Institute & State University (VPI&SU)

EMPLOYMENT HISTORY

1985-present

Senior Staff R&D Chemist, R.J. Reynolds Tobacco Company, Winston-Salem, North Carolina

Engaged in surveys to assess ETS exposure and to evaluate indoor air quality. Developed methods and methodology for conducting surveys. Overseen investigations to evaluate ETS mitigation strategies.

1987-1988

Executive Director, Center for Indoor Air Research, Inc. (Position held in conjunction with duties at R.J. Reynolds Tobacco Company)

Was responsible for the technical and administrative oversight of six multidisciplinary contracts investigating indoor air quality issues.

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1978-1985

Senior Projects Manager, Entropy Environmentalists, Inc., Research Triangle Park, North Carolina.

Was nationally recognized expert on the measurement and monitoring of air pollutant emissions from stationary sources. Was Company's Chief Chemist and Quality Assurance Coordinator for projects contracted by U.S. Environmental Protection Agency (EPA). Developed several EPA Reference Methods and procedures for determining emissions. Wrote policy and procedural documents for the U.S. EPA. Managed project teams sampling emissions from stationary sources.

1977-1978

Instructor, VPI&SU, Blacksburg, Virginia.

Taught Freshman Chemistry and Organic Chemistry

1977

Substitute Teacher, Montgomery County School System, Virginia.

Taught science at the Middle School level.

1977

Free Lance Artist, Blacksburg, Virginia.

Was commissioned to prepare visual materials for Freshman Chemistry laboratory program at VPI&SU.

1975-1977

Graduate Teaching Assistant, VPI&SU, Blacksburg, Virginia

Taught laboratory sections for Freshman and Organic Chemistry and Inorganic and Organic Synthetic Chemistry.

1972-1975

Chemistry Teacher, Albemarle High School, Albemarle County, Virginia

Taught general chemistry; was assistant coach for Cross Country, Indoor Track, and Spring Track

AWARDS

Certificate of Teaching Excellence, VPI&SU, 1978
Phi Lambda Upsilon (chemistry honor society), VPI&SU, 1978
Excalibur Award, R.J. Reynolds Tobacco Company, 1989

SCIENTIFIC PRESENTATIONS

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2. Oldaker, G.B. III "Overview of EPA Methods for Stationary Sources," EPA Workshops on Quality Assurance for Emission Measurements, Dallas, TX, and San Francisco, CA, 1979.

3. Oldaker, G.B. III "Introduction to Continuous Emission Monitoring," EPA Workshops, New York, NY; Lexington, MA; Montpelier, VT; Annapolis, MD; Chicago, IL; Minneapolis, MN; Indianapolis, IN; Lansing, MI; Des Moines, IA; Kansas City, MO; Denver, CO; Rapid City, SD; Cheyenne, WY; and Boise, ID, 1978-1984.

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21. Ogden, M.W.; Nystrom, C.W.; Oldaker, G.B. III*; and Conrad, F.W., Jr. "Evaluation of a Personal Passive Sampling Device for Determining Exposure to Nicotine in Environmental Tobacco Smoke," Environmental Protection Agency/Air and Waste Management Association International Symposium. Measurement of Toxic and Related Air Pollutants, Raleigh, NC (5/4/89).

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* Coauthor

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21. Crouse, W.E.; and Oldaker, G.B. III "Comparison of Area and Personal Sampling Methods for Determining Nicotine in Environmental Tobacco Smoke," submitted for publication in *Proceedings of the 1990 EPA/A&WMA International Symposium on the Measurement of Toxic and Related Air Pollutants.*

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PATENT

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Oldaker/Ogden

2021161769

Comments on:

ENVIRONMENTAL TOBACCO SMOKE: A GUIDE TO WORKPLACE SMOKING POLICIES

[Draft] EPA/400/6-90/004

Response Addressing:

Chapter 2: Measuring ETS in the Air and Body

Section: Assessing ETS Exposure

Section: Air Monitoring Studies

Prepared by:

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October 1990

SUMMARY

Chapter 2: Measuring ETS in the Air and Body, ASSESSING ETS EXPOSURE, Air Monitoring Studies provides a distorted, incomplete, and naive view of the stated subject. This section of the Guide, in its present form, guarantees that users will make uninformed and subjective decisions regarding smoking policies. The inaccuracies, limited number of supporting literature, and imprecise word usage indicate either egregiously poor scholarship or a deliberate attempt to misinform. The EPA has failed entirely in the section on **Air Monitoring Studies** to provide a single, representative example of average RSP concentrations in workplaces where smoking is permitted. By using the National Ambient Air Quality Standard (NAAQS) for particulate matter as a point of reference for indoor levels of ETS, the EPA: (a) misinforms the public regarding the intent of the NAAQS and their regulation, and (b) disregards the regulatory process which they are legally required to observe.

Specific comments are provided below.

ITEM 1. After discussing briefly four ways to assess ETS exposure (namely, monitoring the air, measuring biological markers, administering questionnaires, and applying mathematical models), the Guide states at p. 12:

> Since 1981, approximately 50 studies have been done of ETS concentrations in buildings. Using these methods, researchers have found that [a] **ETS diffuses rapidly through buildings, [b] persists for long periods after smoking ends, and [c] represents one of the major sources of indoor particulate pollution.**

COMMENTS

1. **Incomplete review** The paragraph lacks completeness. Air monitoring studies were done before 1981. Indeed, a sufficiently large number of studies existed in 1982 to justify review by Sterling *et al.* [1]. This reviewer recommends that the EPA perform a more thorough review of the literature relating to "air monitoring" for ETS. This reviewer also questions whether 1981 holds any special significance. If this year is important, the EPA should explain why.

2. **Absence of adequate literature citations** The Guide needs literature citations for the "approximately 50 studies" that have been done. This sentence suggests that a fairly large body of information exists on the assessment of exposure to and the physical behavior of ETS. In addition, the sentence suggests that this information presents a consistent picture of the three findings the paragraph summarizes. To this reviewer's knowledge, the literature does *not* provide a picture *consistent* with these findings nor does it generally *support* these findings.

3. **Failure to follow logical process** The EPA also implicitly fails to follow the logical process required to support this paragraph in particular and the contents of the Guide in general. Thus, in attempting to interpret the significance of the reference to 50 studies, this reviewer must question the EPA's technical basis for the Guide. The EPA is an agency bound by scientific and technical principles including observance of the logical framework that the stated findings imply. The logical development of this Guide requires that the EPA first complete the technical and scientific analyses of the issue to support policy. The Technical Compendium drafted earlier by the EPA theoretically could have provided this support. However, because of many technical deficiencies, the draft Compendium fails to achieve this end. Consequently, this reviewer concludes that the EPA has failed to

provide the public with the support for the policy pronounced by the Guide. In simple terms, the absence of adequate support for the Guide shows that the EPA is either putting the cart before the horse or intends to omit the horse altogether. Clearly, it is essential that the EPA prepare a scientifically sound, peer-reviewed technical document to support the Guide.

4. **Implications regarding what the studies measured** The first sentence is misleading because it suggests that the "50 studies" *measured* "ETS concentrations." Because no ideal indicator (or marker or surrogate) for ETS exists, it is incorrect to say that ETS concentrations are measured. Furthermore, because ETS comprises two phases (a particulate phase and a gas phase), *estimating* "ETS concentrations" at a minimum requires measuring two indicators: One for the vapor phase, the other for the particulate phase. Most studies reported in the literature measured a single surrogate of ETS exposure, therefore restricting exposure assessment to only one ETS phase. Few studies (substantially less than 50) have included more than one surrogate that, in principle, could allow estimates of exposure to both phases.

5. **Implications on the quality of the studies** Without literature citations for the "50 studies," this reviewer, and for that matter, the potential users of this Guide, are left to assume that the quality of each of the 50 studies is adequate to support their collective mention. This assumption is highly questionable, and probably false. The literature on ETS measurements shows that studies vary widely in terms of quality. Indeed, the literature documents discredited studies; e.g., Green *et al.* [2] discredited the work reported by Williams *et al.* [3], *which the Guide itself cites.* (See p.70: 73. WILLIAMS, DC., WHITTAKER, JR., JENNINGS, WG. Measurement of nicotine in building air as an indicator of environmental tobacco smoke levels, Environmental Health Perspectives, Volume 60, p. 405-410, 1985.) Inasmuch as one such discredited study is cited in the Guide to support the EPA's position, this

reviewer must question the quality of the "50 studies" which the EPA uses to support the three findings.

6. **Implied meaning of the word "study"** Used in conjunction with the word "study," the phrase "using these methods" is vague and therefore misleading because it implies that the "50 studies" mentioned earlier include those where mathematical models, biological monitoring, and questionnaires were employed. Mathematical modeling of ETS exposure has *not* been validated. An error analysis derived from information presented by the National Research Council [4] demonstrates that some models reported in the literature cannot provide reliable predictions of ETS exposure (see review by Drs. Sears and Cole included in the Company's response). In addition, this reviewer is unaware of any study where questionnaires were employed that pertained to any of the three findings (identified as a, b, and c under **Item 1.**) Indeed, this reviewer fails to see how questionnaires could be employed scientifically to address any of the three findings.

7. **Implied pertinence of buildings studied** Without citations for the "50 studies," the user of the Guide is has to assume that the buildings studied are pertinent to the needs and interests of "government and private sector decision makers," the intended users of the Guide. This probably would be an incorrect assumption. Given that the Guide relies heavily on citations relating to studies of private residences (see the paragraphs below in the section titled **Air Monitoring Studies**), this reviewer questions the general pertinence of the "50 studies" mentioned. Clearly, the Guide would serve the needs of its intended users better by discussing studies carried out in workplaces.

ITEM 2. The Guide states on p. 12 under **Air Monitoring Studies:**

> "However, studies show that where smoking is permitted, ETS is the major contributor to RSP in indoor air.[27]"

COMMENTS

1. **General** This statement is false. Additionally, semantic carelessness leads to the reasonable conclusion that the intent of the sentence is to misinform.

2. **Inappropriateness of the word "studies"** The word "studies" does not agree in number with the literature citation, which describes a *singular* study. Clearly, this sentence, which makes a very strong point, demands a commensurately strong citation of the supporting literature.

3. **ETS not "the major contributor"** The results presented and cited (SPENGLER, JD., DOCKERY, DW., TURNER, WA., WOLFSON, JM., FERRIS, BG, Jr. Long-term measurements of respirable sulfates and particles inside and outside homes. Atmospheric Environment 15(1): 23-30, 1981) [5] do not support the finding that "ETS is *the major contributor* to RSP in indoor air." For example, Table 2 in that publication shows a mean indoor RSP concentration of 24.4 $\mu g/m^3$ for 35 homes with no smokers. The mean concentration shown for 15 homes with one smoker is 36.5 $\mu g/m^3$. If one assumes that RSP from ETS accounts for the difference between the two results, then ETS contributes 12.1 $\mu g/m^3$ to the total RSP, 36.5$\mu g/m^3$, in the homes with one smoker. This contribution represents 33.2% of the total. "The major contributor?" No, hardly. This reviewer recommends that the authors revise this sentence to be accurate.

4. **Insufficient data to support policy** This reviewer concludes that the study by Spengler *et al.* [5] contains insufficient data to support generalization about the contribution of ETS to RSP levels in homes. Thus, the study reports results from measurements of 55 homes located in six cities. Of these, 35 were identified with no smokers, 15, with one smoker, and 5, with "2+" smokers.

5. **Pertinence of homes to users** As mentioned above (**ITEM 1., COMMENT 7.**), measurements of ETS exposures in homes is not pertinent to those places, e.g., workplaces, which would affect the users of the Guide.

6. **Inappropriate use of the word "permitted"** In the sentence, use of the word "permitted" is inaccurate, inappropriate, and misleading. This reviewer is led to question the authors' motives. Users of the Guide could interpret this sentence to mean that studies were conducted in public places because permission to smoke would be an issue there. Few users would review the footnotes to learn the title of the paper cited; fewer still would read the paper itself. Why is it then that the authors used the phrase "where smoking is permitted" rather than, for example, the phrase "in homes where smoking occurred"?

ITEM 3. The Guide states in several places that:

> ETS diffuses rapidly through buildings.

[See p.3, Measuring ETS in the Air and Body; p. 12 under ASSESSING ETS EXPOSURE; and p.22 under CHAPTER 5: Reducing Exposures to ETS.]

COMMENTS

1. **Misuse of the term diffusion** This reviewer assumes that the EPA means dispersion rather than diffusion. Diffusion relates to motion associated with molecular properties of matter. Diffusion of RSP is therefore necessarily slow. The EPA should use the term "dispersion" to be technically accurate.

2. **Failure to address the effects of dilution** Assuming a value for "rapid," one can argue the truth of this statement based upon fundamental principles of physical chemistry. However, such an argument would address only *part* of the truth. Through omission, the statement misrepresents the science relating to ETS exposure and is therefore misleading. Put simply, *rapid dispersion* must be accompanied by great and equally *rapid dilution.* Experimental support for the relation between dispersion and dilution comes from a comparison of measurements of ETS indicators in smoke plumes with measurements of the same indicators in field settings. Although experiments verify the relation between dispersion and dilution, experimental support for the rapid dispersion of ETS through buildings is meager and ambiguous with respect to implications for ETS exposure. The literature contains very few studies where air monitoring was employed to investigate the matter of the rapid ETS dispersion in buildings. Reported studies involving mathematical modeling assume *a priori* the untested postulate that dispersion is rapid, and are therefore logically inappropriate for addressing the issue. The fundamental problem, however, is that none of the air monitoring studies reported in the literature employed indicators of ETS exposure that were capable of providing unambiguous results regarding dispersion of ETS. Studies that monitor either RSP or CO as indicators are incapable of adequately accounting for non ETS sources. Studies that monitor the air for nicotine or that measure biological markers (and only cotinine, a nicotine metabolite, is viable) indicate nicotine vapor exposure only and not exposure

to the particulate phase of ETS. For example, Nelson *et al.* [6] have shown from field studies the presence of residual nicotine in the absence of ETS RSP.

The matter of dilution raises a related question: What is the *de minimis* level of an indicated ETS exposure? Is it the EPA's policy that any measurable amount of an ETS indicator is evidence of biologically significant exposure? These are both critical questions. With enough effort, scientists can find those stray molecules of ETS indicators that originate, for example, from the clothes and bodies of smokers who occupy environments, yet do not smoke there. What would the EPA's position be if, for example, nicotine was detected in the ambient air in a park or on a street corner?

ITEM 4. The Guide states in several places:

[ETS] persists for long periods after smoking ends.

(For example, see p. 3 under **Key Points** and p. 12 under **ASSESSING ETS EXPOSURE.**)

COMMENT

1. **Failure to address dilution** The issue of persistence is closely linked to the issue of the rapid "diffusion" of ETS commented upon above. Major questions in this regard include:

(a) How long does ETS persist in buildings? The EPA is obligated to provide some quantification of this point.

(b) What literature supports this finding and why does the Guide not cite such necessary supporting literature? Again, it is incumbent upon the EPA to provide supporting literature.

ITEM 5. The Guide states at p.12 under **Air Monitoring Studies:**

However, neither type of monitor measures all the components of ETS because the number of constituents is too large.

COMMENT

1. **Failure to adequately identify limiting factors** This statement is incomplete and inaccurate because it implies that monitoring is limited only by the large number of ETS constituents. The more important limiting factors include:

   (a) the unavailability of sufficiently validated methods for determining constituents in ETS collected from representative situations;

   (b) sampling constraints, for example, detection of most constituents requires sampling exceedingly large volumes of air, which is impractical; and

   (c) most ETS constituent concentrations (*which are postulated to exist based upon their identification in mainstream and sidestream smoke*) are below the limits of detection for those relatively few cases where methods are available.

To be complete the EPA must address these factors.

ITEM 6. Following the above sentence, the Guide states:

> Instead, **surrogates** are used, chemicals that are accurate indicators of the presence and quantity of ETS. The most commonly used surrogate is respirable suspended particles (RSP).

COMMENTS

1. **Failure to address adequately the limitations of surrogates** Both these sentences are inaccurate. Currently, the scientific community lacks an adequate understanding of the reliability of *all* the ETS surrogates (or indicators) employed. The accuracy of RSP and nicotine (and therefore by extension, cotinine in body fluids) as surrogates for ETS exposure is the focus of current (and as yet, incomplete) research. Scientists know that RSP is not an *accurate* indicator of exposure to ETS because it lacks specificity. For example, studies of offices and restaurants where RSP is apportioned for ETS show that RSP measurements by themselves overestimate average ETS exposure by roughly 200% [7]. Thus, stating that RSP is the most commonly used surrogate of ETS is misleading because it implies that it must be reliable because it is commonly used. This logic is false.

2. **RSP not most commonly used surrogate** Moreover, complete review of the literature demonstrates that RSP is not the most commonly used surrogate of ETS exposure. Clearly, the EPA's statement shows that the EPA has neglected a sizable portion of the literature. Such neglect strongly suggests that the EPA is arbitrary in its review of the literature.

3. **Nicotine most commonly used surrogate** Nicotine, rather than RSP, is the most commonly used indicator of exposure to ETS. This reflects its specificity for ETS, its general presence at measurable levels in indoor air, and the

availability of validated methods for its measurement. Nicotine, however, is deficient because it indicates exposure to the vapor phase of ETS. Thus, a complementary indicator, specifically for exposure to the particulate phase, is required to draw conclusions regarding exposure to ETS. Ultraviolet particulate matter (UVPM) [8], the most commonly used indicator of the particulate phase of ETS, fills this need. The EPA has neglected entirely the literature where UVPM has been employed as an ETS indicator. (See, for example, [7, 9, 10, 11, 12, 13].) It is the EPA's responsibility to ensure that the literature is adequately presented; the EPA has failed to do so.

4. **RSP not a chemical** Finally, RSP is not a chemical; it is a physical description of matter. The EPA has failed to provide an accurate rendering of a basic scientific principle relating to the physical properties of ETS.

ITEM 7. The Guide states at p. 12 under **Air Monitoring Studies:**

> RSP refers to tiny particles, small enough to be inhaled deeply into the lungs, that are present in all air.

COMMENT

1. **Failure to address particle deposition.** This sentence presents part of the technical picture and thus is apt to misinform the users of the Guide, who can reasonably assume that RSP thus inhaled is deposited deeply and completely in the lungs. Rather, particle deposition is quite limited: according to the National Research Council [4], approximately 10% of RSP is deposited. In addition, this sentence does not adequately distinguish between exposure and dose. The EPA should provide a complete review of the issues relating to exposure and dose relative to RSP from ETS.

ITEM 8. The Guide states on p. 12 under **Air Monitoring Studies:**

> Stationary air monitor studies have compared RSP levels in the homes of smokers and nonsmokers. They found that each smoker generates 25 to 35 micrograms of RSP per cubic meter of air ($\mu g/m^3$). Homes with two or more heavy smokers frequently exceed the federal 24-hour outdoor particle standard of 260 $\mu g/m^3$. In homes with heavy smokers, short-term particulate concentrations of 500 to 1,000 $\mu g/m^3$ are not uncommon.[28]

COMMENTS

1. **Pertinence** As discussed above (**ITEM 1, COMMENT 7; ITEM 2, COMMENT 5**), homes are not pertinent to the users of the Guide. The comments above hold.

2. **Ambiguous citation** The location of literature citation number 28 is ambiguous. Does this citation refer to the entire paragraph or a part of it?

3. **Inadequate technical support for data** The sentence is vague in regard to the range of RSP generated by a smoker. For example, what is the averaging time for this result? Also, what is the uncertainty associated with this range? These are important questions for the users of the Guide and the EPA should provide answers.

4. **Inappropriate use of the word "generated"** The study supplying the range of RSP "generated" by a smoker did not measure RSP generation; rather, the range came from a comparison of RSP in smokers' and nonsmokers' homes. Thus, strictly speaking the phrase should read each smoker was *associated* with

an increase of 25 to 35 $\mu g/m^3$ RSP relative to homes of nonsmokers. The EPA should revise accordingly.

5. **Failure to provide adequate reference levels of RSP** The paragraph lacks perspective and is therefore misleading. The EPA fails to present data on the levels of RSP in nonsmokers' homes.

6. **Representativeness of smoke generation values** The paragraph is misleading because it implies that smoke generation as estimated in the home environment is representative of smoke generation in the environments (i.e., workplaces) of interest to users of the Guide. Based upon differences in ventilation rates between the two general environmental categories (namely, homes and public places), one must conclude that such representativeness is lacking. If the EPA uses this example of smoke generation for homes, it must provide the rationale for the applicability of such information to public places.

7. **"Heavy smoker" undefined** The Guide is ambiguous in its use of the term "heavy smoker." Without some quantification of this term, the users of the document are left to speculate (perhaps subjectively) on the extent smokers might affect air quality.

8. **Representativeness of situations with multiple smokers** Addressing the matter of homes occupied by two or more smokers, raises a related issue. In those environments of interest to the users of the Guide, to what extent are situations encountered where rooms are occupied by more than one smoker? Simple demographics argue that these situations would occur rather infrequently, a situation which calls into question the pertinence of the issue of two or more smokers in home environments. For those environments of interest to the users of the Guide, it is also probable that for those few cases where more than one smoker occupies a room there exists an equal and

diminishing probability that nonsmokers will be present. The EPA should provide the users of the Guide information regarding the prevalence of conditions in public places where nonsmokers find themselves in rooms occupied by two or more smokers.

9. **Inapplicability of NAAQS** The federal 24-hour outdoor standard is inapplicable when discussing indoor exposures to RSP. *By offering this standard as a point of reference, the EPA (a) misinforms the public regarding the intent of such standards and their regulation and (b) disregards the regulatory process which they are legally required to observe.* Thus, users of the Guide may naively assume that the proper regulatory process has been followed. A proper regulatory process must include preparation of criteria documents, development of standards from measurements made in all indoor environments, and application of Reference Methods for assessing whether an exceedance occurred. (But assuming home measurements are relevant to the issue, then the other side of the issue is: to what extent is the federal 24-hour standard exceeded in homes of nonsmokers?)

10. **Implications of exceedances** The sentence dealing with the issue of exceeding the 24-hour standard implies that levels below 260 $\mu g/m^3$ are acceptable inasmuch as they do not exceed the standard. Is this the EPA's intent?

11. **Failure to identify averaging times and probabilities** The sentence "In homes with heavy smokers, short-term particulate concentrations of 500 to 1,000 $\mu g/m^3$ are not uncommon" is vague and misleading. Without some quantification of both the averaging time for these measurements and the probability of "not uncommon," the reader must speculate regarding the implications of this statement. In addition, presenting such information without explaining that environmental data are generally log normally distributed will lead most uninformed readers to assume that average levels

lie somewhere near the midpoints of the implied range, namely, from 250 to 500 $\mu g/m^3$, an assumption which is false.

ITEM 9. The Guide states on p. 12 under **Air Monitoring Studies:**

> Studies of public buildings duplicate these findings.

COMMENT

1. **Lack of support for "duplication"** This sentence, because of the vague meaning of the phrase "*these* findings," does not and cannot communicate effectively. Additionally, the sentence contains inaccuracies. For example, to this reviewer's knowledge, the literature does *not* support the position that the finding regarding the contribution of smokers to RSP levels presented in connection with homes is duplicated in public buildings. The EPA should provide explicit support for this point, if indeed such support exists. The comments made in connection with the preceding paragraph (under **ITEM 8**) also apply (with the exception of the issue of pertinence) in view of the stated position that results from studies in public places are duplicated by results from studies done in homes.

ITEM 10. The Guide states on p. 12 under **Air Monitoring Studies:**

> Levels [of RSP] in non-smoking buildings, such as churches, libraries and museums, had low levels of RSP. By contrast, restaurants, bars and bus stations, where smoking was permitted, had RSP levels ten to twenty times as high.[29,30]

COMMENTS

1. **Pertinence** The selection of churches, libraries, and museums for purposes of comparing RSP levels is inappropriate for the users of the Guide. These environments are places where smoking either does not occur because of custom or where smoking is generally prohibited because of fire safety or preservation concerns. The users of the Guide are highly unlikely to find themselves having to make decisions regarding smoking policies in these environmental categories.

2. **Ineffective communication** Unquantified use of the word "low" in connection with the levels of RSP in churches, libraries and museums is vague. A similar argument applies to the phrase "levels of RSP in restaurants, bars and bus stations ... had RSP levels ten to twenty times as high." The EPA should provide values for the levels of RSP measured.

3. **Inappropriate and inaccessible literature citation** Literature citation number 29 is inappropriate for this document [MIESNER, EA. et al. Report to the U.S. Environmental Protection Agency, Cooperative Agreement No. CR 813526-01-0, Harvard School of Public Health, 1988]. This paper is essentially inaccessible to the users of the Guide as well as to this reviewer. This reviewer, in addition, questions whether this paper has been peer-reviewed. Moreover, the EPA library in the Research Triangle Park, NC was unable to locate this paper. Thus, because the Guide fails to provide a complete bibliography, thorough review is not possible.

Nevertheless, this reviewer does have available two reports by Miesner *et al.* which have subject areas relevant to the Guide: Miesner, E.A. *et al.* [14]; and Miesner, E.A. *et al.* [15]. In addition, both reports identify the same Cooperative Agreement number. If these are substantively the same as that

cited in reference number 29, the EPA should cite one or both of these instead, because they are generally accessible to the users. Finally, this reviewer will assume that these two papers by Miesner *et al.* [14, 15] are substantively the same for purposes of reviewing the Guide.

4. **Inappropriate and biased choice of environments for comparison** The EPA has selected environmental categories which represent two extremes of RSP concentrations which exist in field settings, and has compared RSP levels for these categories on a relative basis. This reviewer seriously questions the EPA's objectivity in offering this comparison because it violates simple logic and scientific principles, and because it too strongly resembles advertising hyperbole. If a comparison is to be made, objectivity demands that an absolute reference value, e.g, an RSP concentration, be provided. The EPA has failed to provide such a reference concentration. Indeed, the identities and contributions of non ETS sources of RSP will differ substantially among such environmental categories and, as stated before, RSP is not specific for ETS; thus, gross errors will be introduced if consistent environmental categories are not compared. The choice of environmental categories for the comparison is a variation on the elementary theme of "apples and oranges." Clearly, if the EPA is to make such comparisons, logical principles demand that comparisons be made in terms of consistent environmental categories; e.g., RSP in offices where smoking is not permitted relative to offices where smoking is permitted.

5. **Quality of Reference Number 30** The quality of the work described by reference number 30 is poor. The reference fails to address quality assurance relative to the calibration of the device used to monitor RSP. The device used is subject to substantial bias (overestimating levels of RSP) if not calibrated against ETS. Furthermore, corrections for ambient contributions of RSP were not applied consistently across environmental categories. Finally,

averaging times varied by an order of magnitude for the measurements made. Thus, comparisons based upon this reference are invalid.

ITEM 11. The Guide states on p. 12 under **Air Monitoring Studies:**

> The highest RSP levels were found in designated smoking areas, where the level of RSP correlated with the number of cigarettes smoked.

COMMENTS

1. **Undefined environmental category** The EPA does not make clear where the RSP concentrations occurred. The sentence implies that measurements were made in restaurants, bars and bus stations. The EPA should identify the environmental category for the user. Based upon the assumption stated above and the absence of measurements of such areas reported by reference number 30, this reviewer suspects that the environmental categories include one office and one clinic. If this assumption is correct, then the sentence also is misleading. Thus, the data in Table III of the report by Miesner *et al.* [15] do not support the position that the highest RSP levels were found in designated smoking areas. That paper contains the following sentence: "The two highest concentrations for all three instruments were in the designated smoking rooms of non-smoking buildings." This reviewer is left to assume that the two highest concentrations measured are different from the two highest concentrations reported. If all these assumptions are correct, then the EPA has failed to account adequately for the averaging time factor in summarizing and comparing results. To communicate adequately, to be consistent, and to provide valid comparisons, the EPA must address the comments above. Furthermore, this reviewer seriously questions the representativeness of two results for providing an adequate picture for the users of this Guide for

purposes of understanding levels of RSP in smoking areas in general. Thus, if the objectives of this Guide are to be met, results from a survey of RSP levels in designated smoking areas are necessary.

2. **Unquantified RSP level** The phrase "highest RSP levels" does not communicate effectively because the RSP level is unquantified. The EPA should provide the reader with a value.

3. **Pertinence** This reviewer questions the pertinence of discussing RSP levels in designated smoking areas to the users of the Guide. One would reasonably assume that the exposure of nonsmokers to ETS would not be an issue here, because such exposure would be voluntary. Similarly, smokers would voluntarily choose to occupy such areas. Furthermore, smokers' exposure to ETS in designated smoking areas is insignificant relative to mainstream smoke exposure. Additionally, even the Guide offers as a mitigation strategy the designation of smoking areas. This reviewer recommends that the EPA state explicitly the pertinence of RSP levels in designated smoking areas to the needs of the users of the Guide.

4. **Undefined designated smoking area environment** If the EPA is citing a limited number of examples of RSP concentrations in designated smoking areas, then the Agency must clearly define the environmental conditions. Without this information, the users of the Guide cannot adequately interpret the results. The following information is needed: Average number of smokers, smoking rate (e.g, the number of lit cigarettes per number of occupants), room volume, ventilation rate (for example, in units of air changes per hour), and the averaging time for the measurement.

5. **Implications regarding modeling** The item about the correlation between RSP and number of cigarettes smoked is revealing because it represents a tacit

admission regarding the limited applicability of models used to predict exposure to ETS RSP. Put simply, models provide reasonable correlations only under conditions where ETS levels are extraordinarily high relative to those exposures encountered by nonsmokers.

ITEM 12 The Guide states on p. 12 under **Air Monitoring Studies:**

> One office building had RSP levels of 11 $\mu g/m^3$ in its nonsmoking offices, and 520 $\mu g/m^3$ in a smoking lounge.

COMMENTS

1. **Failure to identify representative, pertinent, average RSP levels in areas where smoking is permitted** Yes, no doubt one could measure RSP in an office building and obtain such values; however, the important matter for the users of the Guide is the average levels of RSP encountered in offices and other public places where smoking is *permitted* as distinguished from *designated*. This reviewer is seriously concerned about the absence of such needed information in the Guide *in general* and is unable to understand why **the EPA has failed entirely in the section on Air Monitoring Studies to provide a single, representative example of an average RSP level in a place where smoking is permitted that is pertinent to the needs of the intended users.** Lacking such information on average RSP levels, a reasonable person can conclude that the Guide is a propaganda vehicle, which clearly should not be the intent of the U.S. EPA. The EPA must provide the users of the Guide with this information.

2. **Unusually low concentration of RSP in nonsmoking area** The concentration, 11 $\mu g/m^3$, is unusually low even for a nonsmoking area. The

representativeness of this value is open to speculation. It is highly probable that many users of the Guide will interpret this value as the expected average RSP concentration in nonsmoking offices. To inform the users of the Guide adequately, the EPA must provide average RSP concentrations expected in nonsmoking offices.

3. **Policy by anecdote** This sentence presents results from a *single* pair of data. An informed scientist could not support the position that these two data from a single set of measurements could adequately represent RSP levels in nonsmoking *versus* designated smoking areas. Because this sentence relies on so few data, it can be described as scientific anecdote. ***Anecdote, even if scientific, cannot support policy, which is the purpose of the Guide.*** If this sentence is to remain, the EPA must provide scientific support. This comment applies equally well to many similar examples in the **Air Monitoring Studies** section.

ITEM 13. The Guide states on p. 12 under **Air Monitoring Studies:**

> In the smoking section of an airplane, RSP levels were five times higher than in the nonsmoking section, reaching 1,000 $\mu g/m^3$.[32]

COMMENTS

1. **Ad absurdum argumentation and failure to provide adequate literature support** The U.S. Department of Transportation performed the most comprehensive study of air quality in passenger cabins of commercial aircraft to date [16]. This study reported many RSP concentrations in nonsmoking sections to below the limit of detection. With the logic employed above, the conclusion can be drawn that RSP levels in smoking sections of aircraft were ∞ times greater than those in nonsmoking sections.

2. **Policy by anecdote** This sentence provides the best example of this in the section. Again, only one reference is cited to support the claim.

ITEM 14. The Guide states at p. 12 under **Air Monitoring Studies:**

> Personal air monitor studies found similar results.

COMMENT

1. **See ITEM 9.**

ITEM 15. The Guide states at pp. 12 to 13 under **Air Monitoring Studies:**

> Nonsmokers who were exposed to smokers recorded significantly higher levels of RSP than did those who were not exposed. This was true for children with smoking parents (compared to children of nonsmokers), and for adults exposed to smoke both at home or at work.[33, 34]

COMMENT

1. **See: ITEM 2, COMMENT 5; ITEM 8, COMMENT 5; and ITEM 10, COMMENT 2.**

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EDUCATION

1972, B.A., Chemistry, University of Virginia
1979, Ph.D., Chemistry, Virginia Polytechnic Institute & State University (VPI&SU)

EMPLOYMENT HISTORY

1985-present

Senior Staff R&D Chemist, R.J. Reynolds Tobacco Company, Winston-Salem, North Carolina

Engaged in surveys to assess ETS exposure and to evaluate indoor air quality. Developed methods and methodology for conducting surveys. Overseen investigations to evaluate ETS mitigation strategies.

1987-1988

Executive Director, Center for Indoor Air Research, Inc. (Position held in conjunction with duties at R.J. Reynolds Tobacco Company)

Was responsible for the technical and administrative oversight of six multidisciplinary contracts investigating indoor air quality issues.

1978-1985

Senior Projects Manager, Entropy Environmentalists, Inc., Research Triangle Park, North Carolina.

Was nationally recognized expert on the measurement and monitoring of air pollutant emissions from stationary sources. Was Company's Chief Chemist and Quality Assurance Coordinator for projects contracted by U.S. Environmental Protection Agency (EPA). Developed several EPA Reference Methods and procedures for determining emissions. Wrote policy and procedural documents for the U.S. EPA. Managed project teams sampling emissions from stationary sources.

1977-1978

Instructor, VPI&SU, Blacksburg, Virginia.

Taught Freshman Chemistry and Organic Chemistry

1977

Substitute Teacher, Montgomery County School System, Virginia.

Taught science at the Middle School level.

1977

Free Lance Artist, Blacksburg, Virginia.

Was commissioned to prepare visual materials for Freshman Chemistry laboratory program at VPI&SU.

1975-1977

Graduate Teaching Assistant, VPI&SU, Blacksburg, Virginia

Taught laboratory sections for Freshman and Organic Chemistry and Inorganic and Organic Synthetic Chemistry.

1972-1975

Chemistry Teacher, Albemarle High School, Albemarle County, Virginia

Taught general chemistry; was assistant coach for Cross Country, Indoor Track, and Spring Track

AWARDS

Certificate of Teaching Excellence, VPI&SU, 1978
Phi Lambda Upsilon (chemistry honor society), VPI&SU, 1978
Excalibur Award, R.J. Reynolds Tobacco Company, 1989

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12. Oldaker, G.B. III; Perfetti, P.F.; Conrad, F.W., Jr.; Conner, J.M.; and McBride, R. L. "Results from Surveys of Environmental Tobacco Smoke in Offices and Restaurants," International Conference on Indoor Air Quality, Tokyo, Japan (11/4/87).

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14. Oldaker, G.B. III; and McBride R.L. "Portable Air Sampling System for Surveying Levels of Environmental Tobacco Smoke in Public Places," Symposium on Environment and Heritage. World Environment Day Hong Kong 1988, Hong Kong University, Hong Kong (6/6/88).

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18. Nystrom, C.W.; Oldaker, G.B. III*; and Conrad, F.W., Jr. "Evaluation of Nicotine Passive Sampling Device for Estimating Exposure to Environmental Tobacco Smoke," paper number 47, 42nd Tobacco Chemists' Research Conference, Lexington, KY (10/4/88).

19. Oldaker, G.B. III; Crouse, W.E.; and DePinto, R.M. "On the Use of Environmental Tobacco Smoke Component Ratios," International Conference on the Present and Future of Indoor Air Quality, Brussels, Belgium (2/14/89).

20. Oldaker, G.B. III; and Conrad, F.W., Jr. "Results from Measurements of Nicotine in a Tavern," Environmental Protection Agency/Air and Waste Management Association International Symposium. Measurement of Toxic and Related Air Pollutants, Raleigh, NC (5/4/89).

21. Ogden, M.W.; Nystrom, C.W.; Oldaker, G.B. III*; and Conrad, F.W., Jr. "Evaluation of a Personal Passive Sampling Device for Determining Exposure to Nicotine in Environmental Tobacco Smoke," Environmental Protection Agency/Air and Waste Management Association International Symposium. Measurement of Toxic and Related Air Pollutants, Raleigh, NC (5/4/89).

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* Coauthor

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PATENT

1. McConnell, B.C.; Oldaker, G.B. III; Walsh, R.F. "Air Sampling Device," United States Patent, Patent No. 4,786,472, November 22, 1988.

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III. EDUCATION

1980	B.S. Chemistry, Emory & Henry College, Emory, Virginia
1980	B.S. Applied Mathematics, Emory & Henry College, Emory, Virginia
1985	Ph.D. Analytical Chemistry, Virginia Polytechnic Institute & State University, Blacksburg, Virginia

IV. SCHOLARLY CONTRIBUTIONS

A. Technical Publications: Refereed Journals/Books

1. "Use of Capillary Chromatography in the Analysis of Environmental Tobacco Smoke", Capillary Chromatography: The Applications (submitted November, 1989).

2. "Nasal Trigeminal Responses to Toluene Presented by an Automated Delivery System", Chemical Senses (submitted November, 1989).

3. "Evaluation of a Personal Passive Sampling Device for Determining Exposure to Nicotine in Environmental Tobacco Smoke", Proceedings of the 1989 EPA/AWMA International Symposium on Measurement of Toxic and Related Air Pollutants (submitted May, 1989).

4. "An Intercomparison of Sampling Techniques for Nicotine in Indoor Environments", Environmental Science & Technology (submitted September, 1989).

5. "Collection and Determination of Solanesol as a Tracer of Environmental Tobacco Smoke in Indoor Air", Environmental Science

& Technology 23 (1989) 1148.

6. "Improved Gas Chromatographic Determination of Nicotine in Environmental Tobacco Smoke", Analyst 114 (1989) 1005.

7. "Surveys of Environmental Tobacco Smoke in Offices and Restaurants in New York City", Beitrage zur Tabakforschung (submitted August, 1988).

8. "Apparatus for the Automated Measurement of the Responses of Humans to Odorants", Chemical Senses (submitted August, 1988).

9. "Gas Chromatographic Determination of Nicotine in Environmental Tobacco Smoke: Collaborative Study", J. Assoc. Off. Anal. Chemists 72 (1989) 1002.

10. "Collection and Analysis of Solanesol as a Tracer of Environmental Tobacco Smoke", Indoor and Ambient Air Quality, R. Perry and P. W. Kirk (Eds.), Selper Ltd., London, England (1988) 77.

11. "High Resolution Gas Chromatography of Tobacco Smoke: The Contributions of Kurt Grob", J. of High Resolution Chromatography 11 (1988) 428. (Contribution invited by the Editors for a special memorial issue.)

12. "Gas Chromatographic Determination of Solanesol in Environmental Tobacco Smoke (ETS)", J. of High Resolution Chromatography 11 (1988) 341.

13. "Characterization of Fused Silica Capillary Tubing by Contact Angle Measurements", J. Chromatography 354 (1986) 7.

14. "Synthesis of Siloxane Stationary Phases for Capillary Chromatography", Proc. of the Sixth Int. Symp. on Capillary Chromatography, P. Sandra (Ed.), Dr. A. Huethig, Heidelberg, W. Germany (1985) 149.

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16. "Recent Advances in Gas Chromatography", American Laboratory 17(8) (1985) 15.

17. "Hydrothermal Treatment of Fused Silica Capillary Columns", J. of High Resolution Chromatography 8 (1985) 326.

18. "Improved Quantitative Capillary GC by the Use of CO_2 as Secondary Coolant in Cold On-Column Injection", J. of High Resolution Chromatography 6 (1983) 550.

B. Oral Presentations

1. "Evaluation of Methods for Estimating the Contribution of ETS to

Respirable Suspended Particles", 43rd Tobacco Chemists' Research Conference, Richmond, Virginia, October, 1989.

2. "Use of Capillary Chromatography in the Analysis of Environmental Tobacco Smoke", 198th National American Chemical Society Meeting (invited contribution), Miami Beach, Florida, September, 1989.

3. "Evaluation of a Personal Passive Sampling Device for Determining Exposure to Nicotine in Environmental Tobacco Smoke", 1989 EPA/AWMA International Symposium Measurement of Toxic and Related Air Pollutants, Raleigh, North Carolina, May, 1989.

4. "Collection and Determination of Solanesol as a Tracer of Environmental Tobacco Smoke in Indoor Air", 42nd Tobacco Chemists' Research Conference, Lexington, Kentucky, October, 1988.

5. "Collection and Analysis of Solanesol as a Tracer of Environmental Tobacco Smoke", Indoor and Ambient Air Quality Conference, London, England, June, 1988.

6. "Methods of Analysis for Nicotine, Respirable Suspended Particles (RSP), and Ultraviolet Particulate Matter (UV-PM) in Environmental Tobacco Smoke (ETS): Collaborative Study", 41st Tobacco Chemists' Research Conference, Greensboro, North Carolina, October, 1987.

7. "Methods of Analysis for Nicotine, Respirable Suspended Particles (RSP), and Ultraviolet Particulate Matter (UV-PM) in Environmental Tobacco Smoke (ETS): Collaborative Study", 101st Annual International Meeting of The Association of Analytical Chemists, San Francisco, California, September, 1987.

8. "Improved Gas Chromatographic Quantitation of Trace Levels of Environmental Nicotine", 40th Tobacco Chemists' Research Conference, Knoxville, Tennessee, October, 1986.

9. "Preparation of Inert Fused Silica Capillary Columns for Gas Chromatography Using Hydroxyl-Terminated Polysiloxane Stationary Phases", 38th Southeast Regional Meeting of The American Chemical Society, Louisville, Kentucky, September, 1986. (Paper was an invited contribution to a symposium entitled "Capillary Gas Chromatography Techniques".)

10. "Synthesis of Siloxane Stationary Phases for Capillary Chromatography", Sixth International Symposium on Capillary Chromatography, Riva del Garda, Italy, May, 1985.

11. "Advances in Fused Silica Capillary Column Preparation", 1985 Pittsburgh Conference & Exposition, New Orleans, Louisiana, February, 1985.

12. "Comparison of Injection Reproducibility for Open-Tubular and Packed Column Gas Chromatography", 36th Southeast Regional Meeting of The American Chemical Society, Raleigh, North Carolina, October, 1984.

13. "Sample Preparation by Solid Phase Extraction (SPE)", 36th Southeast

Regional Meeting of The American Chemical Society, Raleigh, North Carolina, October, 1984.

14. "Evaluation of Secondary Cooling in Cold On-Column Injection", 1983 Pittsburgh Conference & Exposition, Atlantic City, New Jersey, March, 1983.

C. Invited Lectures and Seminars

1. "Fundamentals of Supercritical Fluid Chromatography", *Highlands in Chemistry* Seminar Series, Department of Chemistry, Virginia Tech, Blacksburg, Virginia, September, 1988.

2. American Chemical Society Short Course "Gas Chromatography", September, 1988.

3. "SFC and Capillary GC", Graduate course CHEM 5050 - *Industrial Instrumental Analysis*, Department of Chemistry, Virginia Tech, Blacksburg, Virginia, Fall Quarter, 1987.

4. American Chemical Society Short Course "Gas Chromatography", September, 1986.

V. HONORS AND AWARDS

A. 1980 - Blue Key National Honor Fraternity

B. 1984 - American Mensa; Sigma Xi National Research Society

C. 1985 - Virginia Tech Tuition Scholarship; Phi Lambda Upsilon Chemical Honorary Society; Scholarship from Sixth International Symposium on Capillary Chromatography to present results of Ph.D. dissertation research, Riva del Garda, Italy

D. 1987 - Named Associate Referee by the Association of Official Analytical Chemists to study methods for determining nicotine in environmental tobacco smoke

Risner

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Comments on:

ENVIRONMENTAL TOBACCO SMOKE:

A GUIDE TO WORKPLACE SMOKING POLICIES

[Draft] EPA 400/6-90/004

Response Addressing:

Chapter 1: What Is ETS?

Table (page 10):

"Toxic and Cancer Causing Agents in Mainstream and Sidestream Cigarette Smoke"

Prepared by:

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October 1990

SUMMARY: The data table, "Toxic and Cancer-Causing Agents in Mainstream and Sidestream Cigarette Smoke" in Chapter 1, page 10 of The EPA draft document, "Environmental Tobacco Smoke: A Guide to Workplace Smoking Policies," is misleading, inaccurate and unsubstantiated. It should be extensively revised, or deleted from the document.

COMMENTARY: The data table, "Toxic and Cancer-Causing Agents in Mainstream and Sidestream Cigarette Smoke", appearing in Chapter 1 (page 10) of the EPA draft document, "Environmental Tobacco Smoke: A Guide to Workplace Smoking Policies", contains inaccurate and misleading data. The relevance of the table to a discussion of environmental tobacco smoke is questionable. General and specific objections are enumerated below.

General Comments:

1) The table presents data only for **mainstream** and **sidestream** cigarette smoke, not environmental tobacco smoke (ETS), despite the fact that ETS data are available for some of the compounds reported. (See specific comments below.)

2) Because the table presents mainstream and sidestream concentration data within the context of an ETS document, the impression is given that comparable concentration levels exist in ETS. This is misleading and untrue.

[e.g. See specific comments below.]

3) The table is unreferenced in the text!

4) Basis units for the table are missing ("per cigarette"?). Mass units within the table are missing for one entry, incorrect for others.

5) Not all compounds in the table have been reported to be "Toxic and Cancer-Causing Agents" (e.g. ammonia). Consequently the table is mislabeled and deceptive.

6) The specific cigarettes smoked to produce the data in the table are never identified. Neither are references given for the analytical procedures used. As a result, it is impossible to judge the accuracy of the concentrations reported.

Specific Comments:

Because units are incorrect, cigarettes are unidentified and analytical procedures unspecified, it is not possible to ascertain the accuracy of the data.

1) It is nowhere stated that table entries are reported on a "per cigarette" basis.

In addition, there are several "unit" errors in the entries. These are pointed out in the attached comparison table.

2) Literature ETS data (i.e. actual ETS measurements) exist for several of the compounds included in the table; e.g., benzo[α]pyrene [1,2], phenol [3], catechol [3], hydroquinone [3], ammonia [4].

3) Assuming nanogram units (as opposed to the incorrect milligram units appearing in the table), B[a]P concentrations for mainstream of filtered cigarette B (i.e. a cigarette producing the tar values listed for cigarette B) appears high by approximately 250% [5].

4) There are substantial, unexpected differences between the nonfiltered cigarette data in this table and the data in the table on page 10 of the Guide and Table C-2 (page C-19) of the accompanying EPA draft document, "Health Effects of Passive Smoking: Assessment of Lung Cancer in Adults and Respiratory Disorders in Children" ("Health Assessment"). Some differences are detailed in footnotes to the attached comparison table. Others include:

a) Catechol: 41.9 ng MS (Guide) vs. 200 ng MS (Health Assessment)
1.8 SS/MS (Guide) vs. 18 SS/MS (Health Assessment)

b) Ammonia: 7 SS/MS (Guide) vs. 110 SS/MS (Health Assessment)

c) NPYR: 64.5 ng MS (Guide) vs. 20 ng MS (Health Assessment)

1.8 SS/MS (Guide) vs. 18 SS/MS (Health Assessment)

d) NNN: 0.85 SS/MS (Guide) vs. 2 SS/MS (Health Assessment)

Tobacco blend differences may account for some discrepancies, but certainly not to the extent reported.

These mistakes are serious and place into question the validity of the entire table. Without justification for its inclusion, and with so many errors, this table should be deleted from the document.

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2. Salomaa, S., Tuominen, J. and Skytta, E., "Genotoxicity and PAC Analysis of Particulate and Vapor Phases of Environmental Tobacco Smoke," Mutation Research, 204, 173-183 (1988).

3. Risner, C. H. and Cash, S. L., "The Determination of Hydroquinone, Catechol, Phenol and m+p- Cresols in Indoor Air Samples by High Performance Liquid Chromatography," Envir. Tech., 11, 345-352 (1990).

4. Risner, C. H. and Conner, J. M., "A New Device for Collection of Ammonia in Air," to be presented at the American Chemical Society Southeast-Southwest Regional Meeting, Dec. 5-7, 1990.

5. Risner, C. H., "The Determination of Benzo[α]pyrene in the Total Particulate Matter of Cigarette Smoke," J. Chromatogr. Sci., 26 113-120 (1990).

	Table of Guide, page 10			Table C-2, page C-19	
	MS	**SS/MS**		**MS**	**SS/MS**
Nicotine, mg	2.04	2.26		1.4[b]	3
Catechol, µg	41.9	1.4		200	0.7
Benzo[a]pyrene, ng	26.2[a]	2.6		30	3
Ammonia, µg	76.0	7		90	110
N-Nitrosodimethylamine, ng	31.1	24		30	60
N-Nitrosopyrrolidine, ng	64.5[a]	1.8		20	18
N-Nitrosonornicotine, ng	1007	0.85		1500	2
[a] Incorrectly listed as mg instead of ng in Table, p.10					
[b] Incorrectly listed as 14 mg instead of 1.4 mg					

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Presentations:

1. Metal-Ion Interaction with an 8-Quinolinol Silica Gel (QSG) Stationery Phase: Evaluation of Bouded-Phase Loading and Several Mobile Phase Buffers, Charles H. Risner and John R. Jezorek, 35th Southeastern Regional Meeting of the ACS, Charlotte, NC, Nov. 9-11, 1983.

2. Quantitation of Some Tobacco Anions by Eluent Suppressed Anion Exchange Liquid Chromatography, Charles H. Risner, 39th TCRC, Montreal, Quebec, Canada, Oct. 2-5, 1985.

3. The Determination of Benza[a]Pyrene in the Total Particulate Matter of Cigarette Smoke, Charles H. Risner, 40th TCRC, Knoxville, TN, Oct. 13-16, 1986.

4. The Determination of Citrate in Cigarette Paper by Ion Exclusion Chromatography, C.H. Risner, T.R. Conner and R.J. Dunn, 41st TCRC, Greensboro, NC, Oct. 6, 1987.

5. The Determination of Major Phenolic Compounds in Tobacco Smoke, Charles H. Risner and Sheila L. Cash, 42nd TCRC, Lexington, KY, Oct. 2-5, 1988; 40th Southeastern Regional Meeting of the American Chemical Society, Atlanta, GA, Nov. 9-11, 1988; RJR Nabisco Science Forum '88, Winston-Salem, NC, Nov. 15-17, 1988.

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Sears/Cole

2021161821

Comments on:

ENVIRONMENTAL TOBACCO SMOKE: A GUIDE TO WORKPLACE SMOKING POLICIES

[Draft] EPA 400/6-90/004

Response Addressing:

Chapter 2: Measuring ETS in the Air and Body

Section: Mathematical Models

Prepared by:

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October 1990

SUMMARY: The discussion of mathematical modeling in the EPA draft document, "Environmental Tobacco Smoke: A Guide to Workplace Smoking Policies" (The "Guide") is terse to the point of being devoid of useful content. By ignoring the assumptions, approximations and unknowns inherent in the model-building process, the authors present an excessively optimistic assessment of model applicability. Mathematical models developed to date cannot accurately predict ETS exposure. The authors' conclusions are therefore misleading and require substantial clarification.

COMMENTARY: The EPA draft document, "Environmental Tobacco Smoke: A Guide to Workplace Smoking Policies", contains an unacceptably brief and misleading discussion of mathematical models of Environmental Tobacco Smoke (ETS) and their utility (Chapter 2, page 14). The EPA ignored the several types of ETS models, levels of physico-chemical and mathematical sophistication, and, most importantly, significant limitations of their predictive capability. Some models in the literature are suitable only for very restrictive environments (*e.g.*, environments at thermodynamic, chemical and mechanical equilibrium) [1,2]; others are more generally applicable, but are severely limited by computational requirements [3]. The authors' few substantive statements enumerate selective factors which contribute to exposure estimation, without describing how those factors function within a mathematical framework or indicating their relative significance, and without mentioning the many other, well-documented factors that contribute to exposure estimation. Consequently, it is impossible to evaluate the accuracy of a model or the propriety of a particular model's application on the basis of the information provided in the EPA Guide. The conclusion that

"Mathematical models ... have proved to be a reasonable way to estimate ETS exposure" is, at least, scientifically premature and tendentious.

Mathematical models of ETS represent one type of scientific tool which may be applied to the analysis and prediction of ETS exposure. The EPA Guide does not specify the model (or category of model) useful for this purpose. Blanket endorsement of modeling is unwarranted. The applicability of ETS models is limited both by the required precision of experimental input data and by the sophistication of the mathematical description. Extrapolation of models developed for specialized environments to other situations is especially problematic (and unfortunately, commonplace). The EPA Guide fails to consider these important and inherent limitations of mathematical modeling.

A brief review of relevant mathematical models and their experimental verification illustrate the risks associated with the broad, unfounded generalizations made in the EPA draft.

The most rigorous approach to modeling dispersion of environmental cigarette aerosol involves solution of the fundamental equations of aerosol and fluid dynamics [See, *e.g.*, ref. 4 & 5]. The power of this approach lies in its flexibility. The generalized Navier-Stokes equations complemented by the equations of aerosol evolution are adaptable to an infinite variety of environments and climatic conditions. (Often the aerosol dynamics are subordinate to the equations of fluid flow. That is, macroscopic dispersion is emphasized more than microscopic change.) An example of this approach is the aircraft cabin model of R. H.

Horstman [6]. Recently Kim, Yamamoto and collaborators have also initiated office space studies with simplified models of this type [7]. While the necessary chemistry and physics of a particular environment may be implemented in such a model, the numerical computational demands are often severe. There are relatively few ETS models of this type in the literature.

A second, more common approach involves the simplistic description of ETS spaces as "continuous stirred tank reactors (CSTR)" with varying degrees of embellishment (source and sink terms, mixing factors, etc.). Such "compartmental" models often treat complex physical and chemical processes by grossly empirical approximations [1,2]. Models of this type require extensive, accurate input of environmental parameters (*e.g.*, air flow patterns, mass transport coefficients, component concentrations) both for operation and verification. In addition, the compartmental approach makes the great assumption that spatial dispersion of gas phase and particulate ETS components is instantaneous and uniform, regardless of the geometrical dimensions of the study space. Multi-compartment elaborations of the fundamental CSTR unit improve resolution of the data, but require input of still more empirical parameters. Depending upon the complexity of the environment, such models may be grossly inadequate.

Experimental verification of ETS models is also often difficult. Decisions of sampling method, location and duration must be carefully based upon structural detail of the mathematical description. Exposure estimation is a function of many environmental factors.

For more complex environments (*e.g.*, those involving influx/outflux vents, aerodynamic obstacles, chemical interactions, time-dependent sources and sinks, etc.) highly accurate spatio-temporal resolution of components is required. The Guide omits any discussion of the subtle, but important, interplay between model and experiment in the process of verification. All of these points make reliance on current mathematical models to predict ETS exposure very speculative.

As a final comment, the Guide confuses the term "diffusion", which has a specific mathematical and physical meaning, with the broader generic term "dispersion" throughout the document. In addition, few aerosol scientists would agree with the authors that gas phase ETS is defined as particles smaller than 0.1 micron in diameter (Chapter 1, page 7).

The unacceptably brief discussion of modeling in the Guide implies that mathematical models have been developed which are accurate, reliable predictors of ETS exposure - without qualification. This implication is unsubstantiated and premature. We recommend that this serious shortcoming be addressed by including a full and fair assessment of model types and their limitations.

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Smith

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Comments on:

ENVIRONMENTAL TOBACCO SMOKE:

A GUIDE TO WORKPLACE SMOKING POLICIES

[Draft] EPA 400/6-90/004

Response Addressing:

Chapter 3: Health Effects of ETS

Section: Cancer at Other Sites

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SUMMARY: The authors of the EPA's draft document, "Environmental Tobacco Smoke: A Guide to Workplace Smoking Policies" (The "Guide") state, in Chapter 3, page 18, that smoking is related to brain tumors, nasal sinus cancer, genital, breast, endocrine and cervical cancers in adults and brain tumors in infants whose mothers were exposed to ETS while pregnant. Reference to the alleged relationship between smoking or ETS and those cancers is inappropriate because epidemiologic studies cannot demonstrate a causal relationship and deficiencies in the studies call into question the authors' conclusions that ETS may even be associated with these diseases. The Guide should limit its conclusions to the point: "At this point the data are too limited to be conclusive." [The Guide, p. 18].

COMMENTARY: The section "Cancer At Other Sites," referenced six published reports on studies of the relationship between ETS and cancer other than the lung. The studies can be divided into four categories:

1. The 1989 study by Slattery, *et al.* [1] which reported an association between cervical cancer and ETS.

2. The 1982 study by Preston-Martin, *et al.* [2] which reported an association between ETS and childhood brain tumors.

3. The 1984 study by Hirayama [3] which reported that women exposed to spousal ETS are at elevated risk for nasal sinus cancer, brain tumors, breast cancer, and cancer of all sites.

4. Three studies by Sandler, *et al.* [4-6] which reported associations between several cancer types and exposure to ETS.

Comments concerning these four categories of studies are given below:

Analysis of Category 1- The Slattery Study [1]

Zhang, Wynder, and Harris (American Health Foundation, Valhalla, New York), have critiqued the Slattery study in a letter to the editor of JAMA [7]. They concluded that "the classification of passive smoke exposure as a risk factor for cervical cancer seems premature."

Analysis of Category 2- The Preston-Martin Study [2]

This study has at least four major deficiencies:

1. Preston Martin, *et al.* report an increased risk (OR, 1.5; p = 0.03) for childhood brain tumors associated with the mother's living with a smoker during pregnancy. However, they found no association between maternal smoking during pregnancy and childhood brain tumors. Since cigarette smokers are exposed to both mainstream smoke and to much higher levels of ETS than are nonsmokers, cigarette smokers and

their children would be expected to be at an increased risk of brain tumors if the authors' hypothesis were correct.

2. Exposure to several common substances (other than ETS) during pregnancy was also reported to be associated with childhood brain tumors. Exposure to antihistamines (OR, 3.4; p= 0.002), face makeup (OR, 1.6; p = 0.02), diuretics (OR, 2.0; p = 0.03), incense (OR, 3.3; p = 0.005), and cured meat, all were associated with increased risk. The variety of different substances reported to be associated with childhood brain tumors in this study suggests that these results are likely to be due to confounding.

3. Exposure estimates used in the calculations were determined by interview and questionnaire data. Slight inaccuracies in exposure estimates could affect the significance of the relative risk estimates reported in the study.

4. Nine different histological types of brain tumors were combined in a statistical meta-analysis of the data. Meta-analysis must be used with great care. In this study, the authors assume that the different tumors are caused by the same agents. If this (bold) assumption is incorrect, then the "robustness" of any potential correlation is suspect.

Analysis of Category 3 - The 1984 Hirayama Study [3]

In his study, Hirayama reported an increased risk in nonsmoking wives with smoking husbands for nasal sinus cancer, brain tumors, and possibly breast cancer. The reported increase in risk for the spouses of the smokers may be the result of "data dredging". "Data dredging" refers to the process of examining a large number of potential associations by a number of different methods until several associations that fit the hypothesis in question are dredged up by chance [8].

Hirayama examined a large number of associations and found some of them to be positive (lung, brain, sinus, and possibly breast). He also reported that "[n]o significant association was observed with other cancers such as those of the mouth, pharynx, esophagus, stomach, colon, rectum, liver, pancreas, peritoneum, cervix, ovary, urinary bladder, skin, bone, malignant lymphoma, or leukemia, the direction of this trend being evenly distributed to both the plus-side (risk increases with the extent of husband's smoking habit) and the minus-side (risk decreases with the extent of husband's smoking habit)".

Hirayama's results are inconsistent with the results from epidemiology studies conducted on cigarette smokers. Cigarette smokers are exposed to much higher levels of ETS than are ETS-exposed nonsmokers. The hypothesis that exposure to ETS increases the risk of cancer predicts that cancers that are not associated with cigarette smoking should not be associated with ETS exposure. This is not what Hirayama reports. Brain cancer and breast cancer are not associated with cigarette smoking [9,10]. Hirayama finds positive associations between ETS exposure and these non-smoking-associated tumors. Hirayama

found no association between exposure to ETS and a variety of cancers that have been epidemiologically associated with cigarette smoking, including cancer of the esophagus, pancreas, cervix, and urinary bladder [9]. Therefore, Hirayama has not demonstrated an association between ETS and cancer that is consistent with reported epidemiological data in the literature.

Analysis of Category 4 - The Sandler Studies [4-6]

There are several significant lifestyle differences between smokers and nonsmokers. Smokers consume a diet significantly higher in saturated fat and lower in fruits and vegetables than nonsmokers [11-13]. Smokers exercise significantly less than nonsmokers [14]. They also sleep less and consume more alcohol than nonsmokers [15]. Each of these factors is associated with chronic diseases such as cancer and would tend to increase the smokers' relative risk of developing such diseases.

Also, significant differences in lifestyle exist between the spouses of smokers and the spouses of nonsmokers. Perusse, *et al.* [16] demonstrated familial aggregation in physical fitness, coronary heart disease risk factors, and pulmonary function measurements. Other investigators have reported significant dietary differences between the families of smokers and the families of nonsmokers. Sidney, *et al.* [17] reported that the self-reported mean dietary intake of carotene is lower in nonsmokers exposed to ETS at home than in nonsmokers not exposed to ETS at home. Many studies have reported that a low intake or blood level of carotene is a risk factor for cancer, Ziegler, [18]. Sidney, *et al.* [17] also found

a higher proportion of current alcohol consumers and a slightly higher mean body mass index in the exposed subgroup despite its considerably lower mean age.

The studies by Sandler, *et al.* [4-6] do not take into account all of the relevant lifestyle factors that could affect relative risk ratios. One Sandler, *et al.*, study [4] provides several good examples of the failure to adjust for confounding variables. In this study, the authors report "statistically significant risks in relationship to passive smoking are seen for breast cancer, cervical cancer, and endocrine cancers". They reported a two-fold risk of breast cancer in ETS exposed women after adjustment for education, race, age, smoking status, and parental smoking. However, Sandler, *et al.* [4] did not adjust for the four most important breast cancer risk factors other than age: Diagnosis of premenopausal breast cancer in a mother or sister, previous history of proliferative benign breast disease, age at first parity, and diet [19]. Sandler , *et al.* [4] also reported a two-fold risk for cervical cancer associated with ETS exposure after adjustment for age, race, smoking status, and smoking by parents. In this case again, Sandler, *et al.* [4] did not adjust for the most important cervical cancer risk factor: Sexual history of both spouses. Layde and Broste [20] discussed the importance of controlling for this factor in smoking and cervical cancer studies in their 1989 review:

> "In their [sic] summary (IARC's) of the association of cigarette smoking and cervical cancer, the working group stated "for cervical cancer, it is reasonable to suppose that there is a specific causal agent - most probably an infective agent transmitted sexually. Since this agent has not been unequivocally identified, and, in particular, was not included in the studies under review, surrogate measures have been included

to reflect the degree of sexual activity. Smoking is positively related to sexual activity. Any observed crude association between smoking and risk of cervical cancer may be confounded. Since the specific factor by which the analysis should be adjusted is not known, the confounding effect can be removed only partially."

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